IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE MEDICINES COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 11-cv-1285
	)	
MYLAN INC., MYLAN PHARMACEUTICALS INC., and BIONICHE PHARMA USA, LLC,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, District Court Judge:

On February 23, 2011, Plaintiff The Medicines Company ("TMC") filed this action against Defendants Mylan, Inc., Mylan Pharmaceuticals Inc. and Bionche Pharma USA, LLC alleging infringement of United States Patents Nos. 7,582,727 (the "'727 patent") and 7,598,343 (the "'343 patent"). (R. 1, Compl.) On June 21, 2013, Defendants moved for summary judgment of non-infringement or, in the alternative, invalidity. (R. 275, Mot.)

For the following reasons, the Court grants Defendants' motion for summary judgment of non-infringement with respect to the '343 patent but denies it with respect to the '727 patent. The Court also denies Defendants' alternative motion for summary judgment of invalidity with respect to the '727 patent. Finally, the Court grants Defendants' motion for summary judgment on TMC's claim for willful infringement.

BACKGROUND

I. Northern District of Illinois Local Rule 56.1

"For litigants in the Northern District of Illinois, the Rule 56.1 statement is a critical, and required, component of a litigant's response to a motion for summary judgment. The purpose of the local rule is to make the summary judgment process less burdensome on district courts, by requiring the parties to nail down the relevant facts and the way they propose to support them." *Sojka v. Bovis Lend Lease, Inc.,* 686 F.3d 394, 398 (7th Cir. 2012). Local Rule 56.1 assists the Court by "organizing the evidence, identifying undisputed facts, and demonstrating precisely how each side propos[es] to prove a disputed fact with admissible evidence." *Bordelon v. Chicago Sch. Reform Bd. of Trustees,* 233 F.3d 524, 527 (7th Cir. 2000). "The Rule is designed, in part, to aid the district court, which does not have the advantage of the parties' familiarity with the record and often cannot afford to spend time combing the record to locate the relevant information, in determining whether a trial is necessary." *Delapaz v. Richardson,* 634 F.3d 895, 899 (7th Cir. 2011) (internal quotations and citation omitted).

Local Rule 56.1(a)(3) requires the moving party to provide "a statement of material facts as to which the moving party contends there is no genuine issue." *Cracco v. Vitran Exp., Inc.,* 559 F.3d 625, 632 (7th Cir. 2009). The nonmoving party then must file "a response to each numbered paragraph in the moving party's statement, including, in the case of any disagreement, specific references to the affidavits, parts of the record, and other supporting materials relied upon." *Id.* (citing Local Rule 56.1(b)(3)(B)). Pursuant to the Local Rules, the Court will not consider any additional facts proposed in the nonmoving party's Local Rule 56.1(b)(3)(B) response, but must rely on the nonmovant's Local Rule 56.1(b)(3)(C) statement of additional facts. *See Ciomber v. Cooperative Plus, Inc.,* 527 F.3d 635, 643-44 (7th Cir. 2008). The Court

disregards Local Rule 56.1 statements and responses that do not cite to specific portions of the record or that contain legal argument. *See Cracco,* 559 F.3d at 632; *Cady v. Sheahan,* 467 F.3d 1057, 1060 (7th Cir. 2006) (noting that the party's statement of material facts "did not comply with Rule 56.1 as it failed to adequately cite the record and was filled with irrelevant information, legal arguments, and conjecture"); *Chicon v. Exelon Generation Co., L.L.C.,* 401 F.3d 803, 809-10 (7th Cir. 2005) ("A district court does not abuse its discretion when, in imposing a penalty for a litigant's non-compliance with Local Rule 56.1, the court chooses to ignore and not consider the additional facts that a litigant has proposed."). "When a responding party's statement fails to dispute the facts set forth in the moving party's statement in the manner dictated by rule, those facts are deemed admitted for purposes of the motion." *Cracco,* 559 F.3d at 632.

II. Relevant Facts

A. The Parties and the Court's Jurisdiction

Plaintiff TMC is a Delaware corporation with its principal place of business in Parsippany, New Jersey. (R. 277, Mylan L.R. 56.1 Stmt. ¶ 1.) Defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business in Canonsburg, Pennsylvania. (*Id.* ¶ 2.) Mylan Inc. wholly owns the other two Defendants in this case—Mylan Pharmaceuticals Inc. and Bioniche Pharma USA, LLC, now known as Mylan Institutional LLC.[1] (*Id.* ¶¶ 3-4.) Mylan Pharmaceuticals Inc. is a West Virginia corporation with its principal place of business in Morgantown, West Virginia. (*Id.* ¶ 3.) Mylan Institutional LLC's principal place of business is in the Northern District of Illinois. (*Id.* ¶ 4.) The Court has subject matter jurisdiction over

[1] Hereinafter, the Court refers to Defendants collectively as "Mylan" unless otherwise noted.

TMC's patent claims under 28 U.S.C. §§ 1331 and 1338(a), and venue is proper in this District pursuant to 28 U.S.C. §§ 1400(b) and 1391(c).

B. Bivalirudin Final Drug Product

The two patents-in-suit pertain to pharmaceutical formulations of bivalirudin and the process of making bivalirudin. (Compl. at Ex. A (the '727 patent) & Ex. B (the '343 patent); Mylan L.R. 56.1 Stmt. ¶ 21.) Bivalirudin is the active ingredient in TMC's Angiomax® drug product, an injectable anticoagulant used to prevent blood clotting during coronary procedures. (Mylan L.R. 56.1 Stmt. ¶¶ 9-10; R. 290, TMC Resp. Br. at 3.) TMC has sold Angiomax® since 2001. (Mylan L.R. 56.1 Stmt. ¶ 9.) Before expiration of the patents-in-suit, Mylan submitted Abbreviated New Drug Application ("ANDA") No. 202471 to the U.S. Food and Drug Administration ("FDA"), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic equivalent to Angiomax®. (*Id.* ¶ 6.) TMC claims that Mylan's ANDA No. 202471 infringes several claims of the patents-in-suit. (*Id.* ¶¶ 22, 30.)

To create a bivalirudin final drug product, a drug manufacturer first must buy or make the bivalirudin active pharmaceutical ingredient ("API") and then perform a compounding process to adjust the acidity of the bivalirudin API to make the drug suitable for injection in patients. (*See id.* ¶ 13.) The compounding process involves three basic steps. (*Id.*) In the first step, the bivalirudin API is dissolved into a mannitol solution to form a bivalirudin solution. (*Id.*) The resulting bivalirudin solution has a pH level under 3.0, making it too acidic to inject into patients. (*Id.* ¶ 14.) Thus, in the second step, the bivalirudin solution is mixed with a pH-adjusting solution, such as sodium hydroxide, to raise the pH to an acceptable level. (*Id.* ¶¶ 13-14.) In the final step, the mannitol solution and the pH-adjusting solution are removed from the mixture to form the bivalirudin final drug product. (*Id.* ¶ 13.) During this compounding process, one of the

amino acids in the bivalirudin API can convert into an aspartate if the pH level becomes too high. (*Id.* ¶¶ 11-12, 14, 46.) That conversion forms an impurity in the bivalirudin final drug product known as Asp^9-bivalirudin. (*Id.* ¶ 12.)

The bivalirudin final drug product is sold in a single-use vial as a sterile freeze-dried cake. (*Id.* ¶ 9.) The bivalirudin cake must be reconstituted before injection by adding water to it. (*Id.*) Each cake contains 250 milligrams of bivalirudin, 125 milligrams of mannitol (a sugar), and sodium hydroxide (a base) to adjust the acidity of the drug. (*Id.*) Each cake also contains trace amounts of impurities, including Asp^9-bivalirudin. (*Id.* ¶ 12.) High levels of Asp^9-bivalirudin can negatively affect the stability and shelf-life of the bivalirudin final drug product. (*See* '727 patent at col. 2, ll. 16-19; '343 patent at col. 2, ll. 16-19.)

Before the inventions in the patents-in-suit, the compounding process used to make the bivalirudin final drug product resulted in inconsistent and high levels of the Asp^9-bivalirudin impurity. (*See* TMC Resp. to Mylan L.R. 56.1 Stmt. ¶ 24.) The "old" compounding process resulted in at least two batches of TMC's final drug product that failed to meet FDA-approved specifications regarding the amount of allowable impurities. (Mylan L.R. 56.1 Stmt. ¶ 15.) The patents-in-suit pertain to an "improved" compounding process that Drs. Gopal Krishna and Gary Musso[2] developed, which reduced the generation of Asp^9-bivalirudin impurities and made the Asp^9-bivalirudin impurity levels more consistent across batches. (Mylan L.R. 56.1 Stmt. ¶¶ 24, 46.)

[2] As the Federal Circuit has noted, "[i]nventions are created by individuals, not corporations." *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1326 n.1 (Fed. Cir. 2007). The Court, however, refers to "TMC" as shorthand for Drs. Krishna and Musso during its discussion of the history of the patents-in-suit because Drs. Krishna and Musso assigned the inventions in the patents-in-suit to TMC.

C. The Patents-In-Suit

TMC filed both patents-in-suit on July 27, 2008. (*Id.* ¶ 21.) The U.S. Patent and Trademark Office issued the '727 patent on September 1, 2009 and the '343 patent on October 6, 2009. (*Id.*) Both patents-in-suit shares the same title—"Pharmaceutical Formulations of Bivalirudin and Processes of Making the Same"—a nearly identical written specification, and a similar prosecution history. (*See id.* ¶¶ 21, 33, 58-59.) The '727 patent is a product patent (*see* '727 patent at col. 25-28), whereas the '343 patent is a product-by-process patent that claims the same bivalirudin final drug product as the '727 patent but with additional limitations regarding the manufacturing process.[3] (*See* '343 patent at col. 27-28.) Both patents expire no later than January 27, 2009. (Mylan L.R. 56.1 Stmt. ¶ 21.)

1. The '343 Patent

TMC asserts that Mylan has infringed claims 1-3 and 7-11 of the '343 patent. (*Id.* ¶ 22.) Claim 1 is an independent claim, and claims 2-3 and 7-11 depend on claim 1. (*Id.*) Claim 1 states:

> 1. Pharmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1) and a pharmaceutically acceptable carrier, for use as an anticoagulant in a subject in need thereof, said batches prepared by a compounding process, comprising:
>
> (i) dissolving bivalirudin in a solvent to form a first solution;
>
> (ii) efficiently mixing a pH-adjusting solution with the first solution to form a second solution, wherein the pH-adjusting solution comprises a pH-adjusting solution solvent; and
>
> (iii) removing the solvent and pH-adjusting solution solvent from the second solution;

[3] A "true" product claim defines an invention "in terms of structural characteristics only." 3-8 *Chisum on Patents* § 8.05 (Lexis 2013). A "product-by-process" claim, on the other hand, defines an invention "at least in part in terms of the method or process by which it is made." *Id.* The process terms in a product-by-process claim serve as additional limitations in determining infringement. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1294 (Fed. Cir. 2009), *cert denied* 130 S. Ct. 1052 (2010).

> wherein the batches have a pH adjusted by a base, said pH is about 5-6 when reconstituted in an aqueous solution for injection, and wherein the batches have a maximum impurity level of Asp^9-bivalirudin that does not exceed about 0.6% as measured by HPLC.

(*Id.* ¶ 23.)

Each asserted claim in the '343 patent requires "efficient mixing" as part of the compounding process. (*Id.* ¶¶ 22-23; R. 291, TMC L.R. 56.1 Stmt. Add'l Facts ¶ 4.) The '343 patent specification describes various ways to accomplish efficient mixing (*see* '343 patent at col. 9 l. 34 – col. 11 l. 24), and it contrasts efficient and inefficient mixing conditions through examples. (*See id.* at col. 16 l. 15 – col. 25 l. 3.) Example 4, entitled "Effects of Rapidly Adding pH Adjusting Solution to the Bivalirudin Solution Under Inefficient Mixing Conditions – Large Scale Study," describes an example of inefficient mixing (*see id.* at col. 22 ll. 21-31), while Example 5, entitled "Effects of Adding pH Adjusting Solution at a Constant Rate and Under Efficient Mixing Conditions – Large Scale Study," provides an example of efficient mixing. (*See id.* at col. 23 l. 6 – col. 25 l. 3.)

Comparing Examples 4 and 5—as the '343 patent specification does (*see id.* at col. 23 l. 56 – col. 25 l. 3)—highlights the differences between "inefficient mixing" (Example 4) and "efficient mixing" (Example 5). (*See* Mylan L.R. 56.1 Stmt. ¶ 25); *see also* Table 1, *supra.* First, the examples differ with respect to the rate in which the processes added the pH-adjusting solution. The "inefficient mixing" process in Example 4 added the pH-adjusting solution to the bivalirudin solution "either all at once, or rapidly in multiple portions" ('343 patent at col. 22 ll. 37-38; Mylan L.R. 56.1 Stmt. ¶ 26), whereas the "efficient mixing" process in Example 5 added the pH-adjusting solution "at a controlled rate of 2L/min using a peristaltic pump." ('343 patent at col. 23 ll. 21-23; Mylan L.R. 56.1 Stmt. ¶ 29.) Second, the examples differ in the type of mixers used. The "inefficient mixing" process in Example 4 used two paddle mixers ('343

patent at col. 22 ll. 39-40; Mylan L.R. 56.1 Stmt. ¶ 26), while the "efficient mixing" process in Example 5 used one high-shear homogenizer and one paddle mixer. ('343 patent at col. 23 ll. 23-31; Mylan L.R. 56.1 Stmt. ¶ 29.) Third, the examples differ in the rates at which the mixers operated. In Example 4, both paddle mixers operated at a rate of 400-800 rpm ('343 patent at col. 22 ll. 41-42; Mylan L.R. 56.1 Stmt. ¶ 26), whereas in Example 5, the high-shear homogenizer operated at a rate of between 1,000-1,300 rpm and the paddle mixer operated at a rate of 300-700 rpm. ('343 patent at col. 23 ll. 23-31; Mylan L.R. 56.1 Stmt. ¶ 29.) The volume and concentration of the mannitol and pH-adjusting solutions, however, are the same in both examples. (*Compare* '343 patent at col. 22 ll. 32-36 *with id.* at col. 23 ll. 16-20.)

Mixing Conditions	**Example 4's Inefficient Mixing Conditions**	**Example 5's Efficient Mixing Conditions**
Rate of Base Addition	Added either all at once, or rapidly in multiple portions	Added at a controlled rate of 2L/min
Volume and Concentration of Solutions	40 L 0.5 N sodium hydroxide in a 2.64% w/w mannitol solution	40 L 0.5 N sodium hydroxide in a 2.64% w/w mannitol solution
Number and Type of Mixers	Two paddle mixers	One high-shear homogenizer and one paddle mixer
Mixing Speed	Both paddle mixers operated at a rate of 400-800 rpm	The homogenizer operated at a rate of 1000-1300 rpm, and the paddle mixer operated at a rate of 300-700 rpm

Table 1.

The '343 specification summarizes the results of the "inefficient" and "efficient" mixing processes discussed above. (*See* '343 patent at Tbl. 6-9; Mylan L.R. 56.1 Stmt. ¶¶ 27-28.) Batches produced using "efficient mixing" conditions had a lower mean and maximum level of Asp^9-bivalirudin impurities and a smaller standard deviation relative to the mean than batches produced using "inefficient mixing." (*See* '343 patent at Tbl. 8-9.); *see also* Table 2, *supra.* The

"efficiently mixed" batches also had a lower mean and maximum reconstitution time[4] with a smaller standard deviation. (*Id.*)

	Example 4 – "Inefficient Mixing"			Example 5 – "Efficient Mixing"		
	No. of Batches	**Mean ± SD**	**Maximum**	**No. of Batches**	**Mean ± SD**	**Maximum**
Asp^9-bivalirudin	87	0.5 ± 0.4	3.6%	24	0.3 ± 0.1	0.6%
Total Impurities	63	1.4 ± 0.5	3.0%	24	1.0 ± 0.4	2.0%
Largest Unknown Impurity	86	0.3 ± 0.1	0.5%	24	0.2 ± 0.1	0.3%
Reconstitution time	85	30 ± 12	72 sec.	24	18 ± 6	42 sec.

Table 2.

2. The '727 Patent

TMC asserts that Mylan has infringed claims 1-3, 7-10 and 17 of the '727 patent. (Mylan L.R. 56.1 Stmt. ¶ 30.) Claim 1 is an independent claim, and the remaining asserted claims depend on Claim 1. (*Id.*) Claim 1 states:

> Pharmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1) and a pharmaceutically acceptable carrier for use as an anticoagulant in a subject in need thereof, wherein the batches have a maximum impurity level of Asp^9-bivalirudin that does not exceed about 0.6% as measured by HPLC.

(*Id.* ¶ 30.) Each asserted claim in the '727 patent contains a limitation requiring the pharmaceutical batches at issue to have "a maximum impurity level of Asp^9-bivalirudin that does not exceed about 0.6%." (TMC Resp. to Mylan 56.1 Stmt ¶ 32.)

As mentioned above, the '727 patent contains a written specification that is nearly identical to the '343 patent. (Mylan L.R. 56.1 Stmt. ¶ 33.) The '727 patent specification

[4] The "reconstitution time" refers to the amount of time required to prepare the bivalirudin freeze-dried cake for use by, for example, dissolving it in water or saline. (*See* R. 291, TMC Resp. to Mylan L.R. 56.1 Stmt. ¶ 9; '343 patent at col. 12 l.56 – col. 13 l. 6.)

contains the same description of "efficient mixing" as the '343 patent and the same set of examples contrasting "efficient" and "inefficient" mixing conditions. (*See* '727 patent at col. 9, l. 34 – col. 11 l. 30, col. 16 l. 15 – col. 24 l. 35.) Unlike the '343 patent, however, no claims in the '727 patent explicitly refer to "efficient mixing" or any other steps in the bivalirudin compounding process. (*See* '727 patent at col. 25 l. 54 – col. 28 l. 23.)

3. Prosecution History

In addition to sharing similar specifications, the patents-in-suit also share similar prosecution histories. During the prosecution of the '727 patent, TMC's counsel filed a Petition to Make Special under the Accelerated Program ("Petition to Make Special") to have the patent application examined on an expedited basis. (Mylan L.R. 56.1 Stmt. ¶ 58; 278, Greb Decl. Ex. 19.) The applicants also filed a similarly worded Petition to Make Special with respect to the '343 patent. (Mylan L.R. 56.1 Stmt. ¶ 53; Greb Decl. Ex. 20.)

In the Petitions to Make Special, the applicants relied both on the use of "efficient mixing" and the improved characteristics of the Angiomax® drug to distinguish their inventions from prior art. The applicants, for example, distinguished their invention from the old compounding process on the basis of efficient mixing: "In the present invention, various embodiments relate to a less subjective and more consistent process for the mixing of the pH-adjusting solution with the bivalirudin solution. This process involves efficiently mixing the pH-adjusting solution and the dissolved bivalirudin solution, which is not performed in the Applicants' prior compounding process." (*See* Greb Decl. Ex. 19 at 3; Greb Decl. Ex. 20 at 3.)[5]

[5] *See also, e.g.,* Greb Decl. Ex. 19 at 6 ("The '423 application is silent regarding a compounding process via the addition of a pH-adjusting solution to the bivalirudin solution in a controlled manner with efficient mixing as to avoid the formation of Asp^9-bivalirudin during the compounding stage."); *id.* at 9 ("[T]he EMEA publication discloses that the bivalirudin drug substance is compounded, but does not provide a disclosure of how the drug substance was compounded . . . . It is important to note that the manufacture of

The applicants also distinguished the improved Angiomax® drug product from original Angiomax® on the basis of decreased impurity levels and shorter reconstitution times:

> In addition, pharmaceutical batch(es) and pharmaceutical formulation(s) of bivalirudin formed by the new compounding process are distinguished from the batches and formulations of bivalirudin formed by the prior compounding process. The pharmaceutical batch(es) and pharmaceutical formulation(s) associated with the present compounding process are more consistent and have a maximum level of Asp^9-bivalirudin of about 0.6% w/w (a decrease of about 83% compared to the batches or formulations made by the prior process), a maximum reconstitution time of about 42 seconds (a decrease of about 42% compared to the batches or formulations made from the prior process), and a maximum amount of total impurities of about 2.0% (a decrease of about 33% compared to the batches or formulations made by the prior process), for all batches or formulations made by the new process.

(*See* Greb Decl. Ex. 19 at 3; Greb Decl. Ex. 20 at 3.)

D. Mylan's Bivalirudin ANDA Product

Mylan filed an ANDA seeking FDA approval to engage in the commercial manufacture, sale, offer for sale and/or importation of a generic equivalent to Angiomax®. (Mylan L.R. 56.1 Stmt. ¶ 6.) Mylan's ANDA described the finished product specifications for its proposed bivalirudin product and the compounding process Mylan will use to manufacture it. (*Id.* ¶¶ 65-67.) Mylan's compounding process adds the pH-adjusting solution to the bivalirudin solution "all at once," and mixes the bivalirudin solution with a single paddle mixer operating at a speed of 200 rpm. (*Id.* ¶ 68.) The finished product specification in Mylan's ANDA allows for a maximum total of 2.0% Asp^9-bivalirudin impurities in the proposed bivalirudin final drug product (1.0% α- Asp^9-bivalirudin and 1.0% β- Asp^9-bivalirudin). (*Id.* ¶ 66.)

Mylan submitted an exhibit batch of its proposed bivalirudin product to the FDA in conjunction with its ANDA. (*Id.* ¶ 70.) Although the ANDA specifications allow Asp^9-

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these bivalirudin batches were [sic] <u>not</u> performed using the inventive process of the present invention." (emphasis in original)).

bivalirudin impurities of up to 2.0%, the exhibit batch Mylan submitted had an Asp^9-bivalirudin impurity level of only 0.2%. (TMC L.R. 56.1 Stmt. Add'l Facts ¶ 24.) Mylan's contract manufacturer, Biocon Ltd., manufactured the exhibit batch using the same method that Mylan will use to manufacture the proposed commercial batches, except on a smaller scale. (Mylan L.R. 56.1 Stmt. ¶ 71.)

After the FDA approved Mylan's ANDA for filing, Mylan sent notice of the filing to TMC, the holder of the new drug application for Angiomax® and owner of the patents-in-suit. (*Id.* ¶¶ 5-7.) Mylan certified in the notice that (1) it did not believe its proposed bivalirudin product would infringe the patents-in-suit, and (2) it believed that the patents-in-suit are invalid. (*Id.* ¶ 6.) On February 23, 2011, TMC filed this action under the Hatch-Waxman Act, alleging that the manufacture, sale, and offer for sale of Mylan's proposed bivalirudin ANDA product would infringe the patents-in-suit. (R. 1, Compl.)

E. The Court's Claim Construction Opinion

On July 30, 2012, the Court held a claim construction hearing to resolve the parties' disagreements regarding the proper construction of two claim terms: "pharmaceutical batches," which appears in the claims of both patents-in-suit, and "efficiently mixing," which appears only in the claims of the '343 patent. (*See* R. 119, Claim Construction Op. at 4.) Although the parties' originally proposed constructions of "pharmaceutical batches" that differed significantly, the parties ultimately narrowed their dispute during claim construction briefing. (*Id.* at 8.) By the claim construction hearing, the parties' proposed constructions differed in only one respect: Mylan's proposal included the phrase "made by a compounding process," but TMC's proposal did not. (*Id.*) Mylan argued that the addition of the phrase "made by a compounding process"

was necessary to provide an antecedent basis for the term "said process" that appeared later in the definition of pharmaceutical batches. (*Id.* at 9.)

TMC disagreed, contending that "[w]hen viewed in the context of the specification, it is readily apparent that the phrase 'made by said process' refers to the compounding processes described in the patents-in-suit." (R. 117, TMC Claim Construction Sur-Reply at 2.) TMC further argued that if the Court determined that the definition of pharmaceutical batches required an express antecedent basis, the proper inclusion would be "made by a compounding process *of various embodiments of the present invention,*" the verbatim antecedent basis provided in the specification. (*Id.* at 4 (emphasis added).) During the claim construction hearing, though, TMC withdrew its alternate proposal and stated that it "could live with" Mylan's proposed addition of "made by a compounding process" if the Court determined an express antecedent basis was necessary. (7/30/12 Hrg. Tr. 9:15-10:3.)

The Court ultimately construed the disputed terms as follows:

Claim Term or Phrase	**Court's Construction**
"pharmaceutical batches"	"[M]ay include a single batch, wherein the single batch is representative of all commercial batches (see generally, Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAPP 5225.1, Guidance on the Packaging of Test Batches at 1) made by a compounding process, and wherein the levels of, for example, Asp^{9}-bivalirudin, total impurities, and largest unknown impurity, and the reconstitution time represent levels for all potential batches made by said process. 'Batches' may also include all batches prepared by a same compounding process."
"efficiently mix"	"A pH-adjusting solution and the first solution are mixed not using inefficient mixing conditions such as described in Example 4."

SUMMARY JUDGMENT STANDARD

Although Federal Circuit precedent governs substantive issues of patent law at issue here, Seventh Circuit law applies to procedural summary judgment issues. *See, e.g., Shum v. Intel Corp.,* 633 F.3d 1067, 1076 (Fed. Cir. 2010) ("We review grants of summary judgment . . . under the law of the regional circuit, since they present procedural issues not unique to patent law." (citing *Koninklijke Philips Elecs. N.V. v. Cardiac Sci. Operating Co.,* 590 F.3d 1326, 1332 (Fed. Cir. 2010))). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine dispute as to any material fact exists if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986).

In deciding summary judgment motions, "facts must be viewed in the light most favorable to the nonmoving party only if there is a 'genuine' dispute as to those facts." *Scott v. Harris,* 560 U.S. 372, 380, 127 S. Ct. 1769, 167 L. Ed. 2d 686 (2007). The party seeking summary judgment has the initial burden of establishing that there is no genuine dispute as to any material fact. *See Celotex Corp. v. Catrett,* 477 U.S. 317, 323, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). After "a properly supported motion for summary judgment is made, the adverse party 'must set forth specific facts showing that there is a genuine issue for trial.'" *Anderson,* 477 U.S. at 225, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (citation omitted). "[D]istrict courts presiding over summary judgment proceedings may not weigh conflicting evidence or make credibility determinations, both of which are the province of the jury." *Omnicare, Inc. v. UnitedHealth Grp., Inc.,* 629 F.3d 697, 704-05 (7th Cir. 2011) (internal citations omitted).

ANALYSIS

Mylan moves for summary judgment of non-infringement or, in the alternative, of invalidity. Mylan argues that TMC's infringement claims fail because TMC cannot establish two elements of the asserted patent claims. (R. 276, Mylan Opening Br. at 12.) First, Mylan contends that its ANDA compounding process does not use "efficient mixing." (*Id.* at 12-20.) Indeed—Mylan argues—its compounding process is *even more inefficient* than the examples of inefficient mixing described in the patents-in-suit. Because "efficient mixing" is an express limitation of the asserted claims in the '343 patent, Mylan argues that the Court should grant summary judgment of non-infringement with respect to the '343 patent. (*Id.* at 13-15.) Additionally, Mylan asserts that summary judgment is also appropriate with respect to the '727 patent because the term "pharmaceutical batches" incorporates an "efficient mixing" requirement into the asserted claims in the '727 patent. (*Id.* at 15-18.)

Second, Mylan argues that TMC cannot establish that pharmaceutical batches made using Mylan's ANDA process will have a maximum impurity level of Asp^9-bivalirudin that does not exceed 0.6%, as the asserted claims of the patents-in-suit require. (*Id.* at 12, 20-22.) TMC bases its infringement claim on the Asp^9-bivalirudin impurity level of Mylan's exhibit batch. Mylan argues that this single batch result fails to create a genuine factual dispute regarding infringement, and summary judgment of non-infringement is therefore appropriate. (*Id.*)

In Mylan's alternative motion based on invalidity, Mylan argues that if the Court construes the claims of the '727 patent to encompass both "efficient" and "inefficient" mixing, then the asserted claims of the '727 patent are invalid. (*Id.* at 22-26.) According to Mylan, this interpretation would render the asserted claims in the '727 patent invalid on grounds of anticipation, lack of enablement, and lack of written specification. (*Id.*)

Finally, Mylan seeks summary judgment with respect to TMC's claim of willful infringement. (*Id.* at 26-28.) Mylan argues that the filing of an ANDA alone does not support a finding of willful infringement, and even if it did, TMC cannot show that Mylan's actions were objectively unreasonable. (*Id.*)

I. Infringement of the Patents-In-Suit

"To prove literal infringement, the patentee must show that the accused device contains every limitation in the asserted claims." *Riles v. Shell Exploration & Prod. Co.,* 298 F.3d 1302, 1308 (Fed. Cir. 2002) (quoting *Mas-Hamilton Grp. v. LaGard., Inc.,* 156 F.3d 1206, 1211 (Fed. Cir. 1998)). Courts use a two-step analysis to determine whether a product or process literally infringes a patent. First, the court interprets the claims of the patent to determine their scope and meaning. *Presidio Components, Inc. v. American Tech. Ceramics Corp.,* 702 F.3d 1351, 1358 (Fed. Cir. 2012); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). Next, the fact-finder compares the properly construed claims to the allegedly infringing product or process. *Presidio,* 702 F.3d at 1358; *Cybor,* 138 F.3d at 1454. While the first step is a question of law for the Court, the second step is a question of fact. *ActiveVideo Networks, Inc. v. Verizon Comm'cns,* 694 F.3d 1312, 1319 (Fed. Cir. 2012). "If any claim limitation is absent from the [product or process], there is no literal infringement as a matter of law." *Cephalon, Inc. v. Watson Pharms., Inc.,* 707 F.3d 1330, 1340 (Fed. Cir. 2013).

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Voda v. Cordis Corp.,* 536 F.3d 1311, 1324 (Fed. Cir. 2008) (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21, 117 S. Ct. 1040, 137 L. Ed.

2d 146 (1997)). "To support a finding of infringement under the doctrine of equivalents, a patentee must provide particularized testimony and linking argument with respect to the 'function, way, result' test." *Cephalon, Inc.,* 707 F.3d at 1340. That is, the patentee must show that the accused device "performs substantially the same function in substantially the same way with substantially the same result" as claimed in the patent-in-suit. *Energy Transp. Grp., Inc. v. William Demant Holding A/S,* 697 F.3d 1342, 1352 (Fed. Cir. 2012) (quoting *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.,* 559 F.3d 1308, 1312 (Fed. Cir. 2009)).

Because the patentee bears the ultimate burden of proving infringement, whether literal or under the doctrine of equivalents, an accused infringer can prevail on a motion for summary judgment of non-infringement "either by providing evidence that would preclude a finding of infringement, or by showing that the evidence on file fails to establish a material issue of fact essential to the patentee's case." *Novartis Corp. v. Ben Venue Labs., Inc.,* 271 F.3d 1043, 1046 (Fed. Cir. 2001). If the accused infringer meets its burden of establishing grounds for summary judgment, the patentee must then show the existence of a genuine issue of material fact precluding summary judgment. *Anderson,* 477 U.S. at 250-51. The patentee "cannot rest on mere allegations, but must present actual evidence" to avoid summary judgment. *Crown Operations Int'l, Ltd. v. Solutia Inc.,* 289 F.3d 1367, 1375 (Fed. Cir. 2002) (citing *Anderson,* 477 U.S. at 248).

Mylan argues that TMC's infringement claims fail as a matter of law because TMC cannot prove two elements required by each of the asserted patent claims. First, Mylan argues that TMC cannot prove Mylan's compounding process uses "efficient mixing." (*See* Mylan Opening Br. at 11-20.) Second, Mylan argues that TMC cannot prove that pharmaceutical batches made using Mylan's compounding process will have a maximum Asp^9-bivalirudin

impurity level no greater than about 0.6%. (*See id.* at 20-22.) As explained below, the Court grants Mylan's motion for summary judgment of non-infringement with respect to the '343 patent but denies it with respect to the '747 patent.

A. The '343 Patent

1. Mylan's ANDA Compounding Process Does Not Literally Infringe the '343 Patent

The Court has construed "efficiently mixing" in the asserted claims of the '343 patent to mean that "[a] pH-adjusting solution and the first solution"—*i.e.*, the bivalirudin solution—"are mixed not using inefficient mixing conditions such as described in Example 4." (Claim Construction Order at 30.) Mylan argues that TMC cannot establish infringement of the '343 patent because Mylan's compounding process is *more inefficient* than the "inefficient mixing conditions" described in Example 4. (Mylan Opening Br. at 14.) The Court agrees.

The '343 patent contrasts "inefficient" and "efficient" mixing conditions through examples, most notably Examples 4 and 5. Comparing the "inefficient mixing" conditions in Example 4 with the "efficient mixing" conditions in Example 5 reveals the mixing conditions relevant to determining whether a compounding process uses "inefficient" or "efficient" mixing conditions: the rate at which the pH-adjusting solution is added; the type and number of mixers used for stirring; and the rate of stirring. (*Compare* '343 patent at col. 22 l. 21 – col. 23 l. 4 *with id.* at col. 23 l. 6 – col. 23 l. 5.) The "inefficient mixing" process in Example 4 adds the pH-adjusting solution to the bivalirudin solution "either all at once, or rapidly in multiple portions" ('343 patent at col. 22 ll. 37-38; Mylan L.R. 56.1 Stmt. ¶ 26), whereas the "efficient mixing" process in Example 5 adds the pH-adjusting solution "at a controlled rate of 2L/min using a peristaltic pump." ('343 patent at col. 23 ll. 21-23; Mylan L.R. 56.1 Stmt. ¶ 29.) The "inefficient mixing" process in Example 4 uses two paddle mixers ('343 patent at col. 22 ll. 39-

40; Mylan L.R. 56.1 Stmt. ¶ 26), whereas the "efficient mixing" process in Example 5 uses one high-shear homogenizer and one paddle mixer. ('343 patent at col. 23 ll. 23-31; Mylan L.R. 56.1 Stmt. ¶ 29.) Furthermore, in Example 4, both paddle mixers operate at a rate of 400-800 rpm ('343 patent at col. 22 ll. 41-42; Mylan L.R. 56.1 Stmt. ¶ 26), whereas in Example 5, the high-shear homogenizer operates at a rate between 1,000-1,300 rpm and the paddle mixer operates at a rate of 300-700 rpm. ('343 patent at col. 23 ll. 23-31; Mylan L.R. 56.1 Stmt. ¶ 29.)

Mixing Conditions	**Example 4's Inefficient Mixing Conditions**	**Example 5's Efficient Mixing Conditions**
Rate of Base Addition	Added either all at once, or rapidly in multiple portions	Added at a controlled rate of 2L/min
Volume and Concentration of Solutions	40 L 0.5 N sodium hydroxide in a 2.64% w/w mannitol solution	40 L 0.5 N sodium hydroxide in a 2.64% w/w mannitol solution
Number and Type of Mixers	Two paddle mixers	One high-shear homogenizer and one paddle mixer
Mixing Speed	Both paddle mixers operated at a rate of 400-800 rpm	The homogenizer operated at a rate of 1000-1300 rpm, and the paddle mixer operated at a rate of 300-700 rpm

Table 1.

No factual disputes exist regarding the steps involved in the compounding processes described in Example 4 or those in Mylan's ANDA. (*See* Mylan L.R. 56.1 Stmt. ¶ 56.) The only question is whether Mylan's compounding process is as inefficient (or more inefficient) than the compounding process described in Example 4 in the '343 specification. Table 3 compares the relevant mixing conditions of Example 4 and Mylan's compounding process.

Mixing Conditions	Example 4's Inefficient Mixing Conditions	Mylan's ANDA Compounding Process
Rate of Base Addition	Added either all at once, or rapidly in multiple portions	Added all at once
Volume and Concentration of Solutions	40 L 0.5 N sodium hydroxide in a 2.64% w/w mannitol solution	1 L 1.0 N sodium hydroxide (no mannitol)
Number and Type of Mixers	Two paddle mixers	One paddle mixer
Mixing Speed	Both paddle mixers operated at a rate of 400-800 rpm	One mixer operated at 200 rpm

Table 3.

The undisputed facts show that Mylan's compounding process is more inefficient than the "inefficient mixing" process described in Example 4. Mylan uses one paddle mixer instead of two, and its mixer operates at a lower speed than the mixers in Example 4. (*See* Mylan L.R. 56.1 Stmt. ¶ 68.) Furthermore, while Mylan's compounding process always adds the pH-adjusting solution "all at once" (*id.*), the process in Example 4 adds the pH-adjusting solution *either* all at once *or* rapidly in multiple portions.

TMC argues that certain differences between Mylan's compounding process and the "inefficient mixing" process in Example 4 create a genuine dispute of material fact regarding whether Mylan practices efficient mixing. (TMC Resp. Br. at 16-18.) Most notably, TMC argues that the difference in scale between Mylan's compounding process and the process in Example 4 creates a factual dispute regarding the efficiency of Mylan's compounding process. (*Id.*) According to TMC, it is easier to efficiently mix a small volume than a large volume, and thus, Mylan may practice "efficient mixing" despite using fewer paddle mixers and operating those mixers at lower speeds than in Example 4. (*Id.* at 16-17.) As TMC's expert, Dr. Klibanov, phrased it, "[i]t is much easier to uniformly mix milk into your coffee in an eight-ounce cup than [in] a two-gallon pot of coffee." (*Id.* at 17.)

TMC argues that additional differences between Mylan's process and the process in Example 4 also affect the efficiency of Mylan's mixing process. (*Id.* at 17-18.) Mylan's bivalirudin solution contains 3.83% w/w mannitol and its pH-adjusting solution does not contain any mannitol, whereas Examples 4 uses a 2.64% w/w mannitol in both solutions. ('343 patent, col. 22-23.) Additionally, Mylan's process uses 1.0 N sodium hydroxide as its pH-adjusting solution, while Example 4 uses 0.5 N sodium hydroxide. (*Id.*) TMC argues that Mylan's use of a more concentrated pH-adjusting solution would increase mixing efficiency by minimizing the formation of "hot spots." (*Id.* at 17-18.) According to TMC, these factors, along with the difference in scale between Mylan's compounding process and the "inefficient mixing" process used in Example 4, create a genuine issue of material fact regarding whether Mylan "efficiently mixes." (*Id.* at 18.)

The Court, however, construed the term "efficient mixing" to preclude the use of "inefficient mixing conditions *such as described in Example 4*," not just conditions identical to those in Example 4. (Claim Construction Op. at 30 (emphasis added).) Moreover, while the patents-in-suit contain a lengthy discussion about potential ways to achieve "efficient mixing," the factors TMC relies on—scale and the concentration of the mannitol and pH-adjusting solutions used—are not mentioned in that discussion. Volume, sodium hydroxide concentration, and percentage mannitol, in fact, are held constant between Examples 4 and 5. (*Compare* '343 patent at col. 22 l. 21 – col. 23 l. 4 *with id.* at col. 23 l. 6 – col. 23 l. 5.) The patents-in-suit in no way indicate that these constants bear on whether mixing conditions are "efficient" or "inefficient." This is especially true regarding volume since the volume involved in Example 2—another example of "inefficient mixing" conditions contained in the patent specification—is more than two magnitudes smaller than the volumes in Examples 4 and 5, yet the patent does not

indicate that this difference affected "efficiency" in any way.[6] TMC's argument that the differences in scale and solution concentrations between Mylan's compounding process and the "inefficient mixing" process in Example 4 precludes summary judgment therefore fails.

2. Mylan Does Not Infringe Under the Doctrine of Equivalents

TMC asserts that even if Mylan's compounding process does not literally infringe the '343 patent, it infringes under the doctrine of equivalents. (TMC Resp. Br. at 26.) Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Voda,* 536 F.3d at 1324 (quoting *Warner-Jenkinson Co.,* 520 U.S. at 21). To prove infringement under the doctrine, the patentee must satisfy the "function-way-result" test. That is, the patentee must show that the accused device "performs substantially the same function in substantially the same way with substantially the same result." *Energy Transp. Grp.,* 697 F.3d at 1352 (quoting *Crown Packaging Tech.,* 559 F.3d at 1312).

TMC relies on a declaration from its expert, Dr. Klibanov, dated August 16, 2013, to support its argument of infringement under the doctrine of equivalents. (TMC Resp. Br. at 26-28.) As an initial matter, the Court agrees with Mylan that TMC failed to timely disclose Dr. Klibanov's expert opinions regarding the doctrine of equivalents. (*See* R. 292, Mylan Reply Br. at 20-23.) On November 19, 2012, the Court set the following expert discovery deadlines: "Opening expert reports due by 2/8/13. Rebuttal expert reports by 3/8/13. Reply expert reports

[6] Mylan also argues that it does not "efficiently mix" because its compounding process is "at least as inefficient as the other inefficient processes described in the patents-in-suit," including Example 2. (Mylan Opening Br. at 14-15.) The Court agrees with TMC that this argument is irrelevant because the Court's claim construction specifically refers to Example 4, not to Example 2. (TMC Resp. Br. at 19.)

by 4/8/13. All expert discovery shall be completed by 5/8/13." (R. 173.) TMC served three expert reports for Dr. Klibanov, totaling over 127 pages, before the close of expert discovery. (*See generally* R. 288-2, Dr. Klibanov Opening Expert Report; 288-25, Dr. Klibanov Rebuttal Expert Report; 288-21, Dr. Klibanov Reply Expert Report.) Dr. Klibanov did not offer any opinions regarding infringement under the doctrine of equivalents in those reports. In his opening report, Dr. Klibanov purported to "reserve the right" to address the doctrine of equivalents in later reports (*see* Dr. Klibanov Opening Expert Report ¶¶ 92, 162), but he did not offer any opinions on the doctrine of equivalents until over three months after the close of expert discovery. (*See* R. 289, Dr. Klibanov Decl. ¶¶ 43-52.) TMC never requested or received leave to submit an additional, belated expert report for Dr. Klibanov. The Court, therefore, strikes Dr. Klibanov's August 16, 2013 declaration pursuant to Federal Rule of Civil Procedure 37(c)(1).

Even if the Court considered Dr. Klibanov's belated opinions, moreover, TMC's claim of infringement under the doctrine of equivalents fails the second prong of the function/way/result test. Regardless of whether or not Mylan's compounding process performs substantially the same function and achieves substantially the same result as the claimed invention, TMC's claim of infringement under the doctrine of equivalents fails because Mylan's process does not achieve its results "in substantially the same way" as the invention at issue; that is, Mylan's ANDA process does not use "efficient mixing." TMC argues that "Mylan achieves its low Asp^9 result in substantially the same way as the '343 patent because, as discussed above, Mylan does not practice Example 4." (TMC Resp. Br. at 27.) The Court, however, already has rejected this argument. (*See* Part I.A.1, *supra.*)

Additionally, even if Mylan's compounding process did meet the function/way/result test, TMC cannot claim infringement under the doctrine of equivalents because the '343 patent

specification and prosecution history expressly disclaim "inefficient mixing" conditions such as Example 4 in order to get around anticipation by prior art. *See also Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1307 (Fed. Cir. 2011) ("It is well settled that when a specification excludes certain prior art alternatives from the literal scope of the claims and criticizes those prior art alternatives, the patentee cannot then use the doctrine of equivalents to capture those alternatives.") (internal quotation omitted). As discussed above, the '343 patent specification explicitly distinguishes between "efficient mixing" conditions, like those in Example 5, and "inefficient mixing" conditions, like those in Example 4. The "inefficient mixing" conditions described as Example 4, therefore, are not "substantially similar" to the "efficient mixing" conditions used in the claimed invention. *See Retractable Techs., Inc.* 653 F.3d at 1307. Similarly, when arguing for patentability during the prosecution process, TMC distinguished the prior art references by saying that they utilized "inefficient mixing" conditions, rather than the "efficient mixing" conditions of the '343 patent. TMC, therefore, cannot claim that Mylan's compounding process, which is more inefficient than the "inefficient mixing" process in Example 4, is substantially equivalent to the "efficient mixing" process claimed by the '343 patent. *See Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1322 (Fed. Cir. 1999).

3. Mylan Did Not Admit That Its Compounding Process Uses "Efficient Mixing"

TMC next argues that summary judgment of non-infringement is inappropriate because Mylan admitted that its compounding process uses "efficient mixing." (TMC Resp. Br. at 5-6, 20.) TMC, however, fails to point to a single admission by Mylan. Rather, TMC relies on statements that Biocon employees made during the development of Mylan's exhibit batch. (TMC Resp. Br. at 5-7, 20; *see also* R. 288, Fleming Decl. Ex. 7, 11, 28.) Specifically, in one document, a Biocon employee investigating the cause of a "failed" test batch determined that the

high level of Asp^{9}-bivalirudin impurities in the test batch resulted from mixing "without adequate stirring."[7] (Fleming Decl. Ex. 11 at MYL034579.) According to another document, Biocon subsequently performed "experiments . . . to identify a better approach for efficient stirring." (Fleming Decl. Ex. 7.) A third document states that Biocon manufactured the exhibit batch Mylan submitted to the FDA using the "better stirring operation" developed through those experiments. (Fleming Decl. Ex. 28 at BC013418.)

TMC's reliance on these statements is improper for two reasons. First, "a party may not rely upon inadmissible hearsay to oppose a motion for summary judgment." *Gunville v. Walker,* 583 F.3d 979, 985 (7th Cir. 2009). Federal Rule of Evidence 801(d) "classifies a statement as nonhearsay if the statement is offered against a particular party and (1) is made by a person 'authorized by [that] party to make a statement concerning the subject,' or (2) is made by that party's agent 'concerning a matter within the scope of the agency.'" *Carlisle v. Deere & Co.,* 576 F.3d 649, 656 (7th Cir. 2009) (quoting Fed. R. Evid. 801(d)(2)(C)-(D)). TMC, however, has not offered any evidence that Mylan authorized Biocon to make the statements at issue. In addition, although TMC implies that Biocon was Mylan's agent and made those statements within the scope of that agency relationship, TMC offers no evidence to establish this purported agency relationship between Biocon and Mylan.

Under Illinois law, "[t]he determination of whether a person is an agent or independent contractor rests upon the facts and circumstances of each case." *Lawlor v. North Am. Corp. of Ill.*, 2012 IL 112530, ¶ 44, 368 Ill. Dec. 1, 983 N.E.2d 414 (Ill. 2012). Illinois law provides a

[7] Although TMC included full images of the Biocon documents it cited, including the "Biocon" label in the upper left corner of the documents, in TMC's additional statement of facts (*see* TMC L.R. 56.1 Stmt. of Add'l Facts ¶ 21), the excerpts that appear in the body of TMC's brief conspicuously, and misleadingly, omitted the "Biocon" label. (TMC Resp. Br. at 6.)

number of factors that courts should consider in determining whether a person qualifies as another's agent:

> [T]he cardinal consideration is whether that person retains the right to control the manner of doing the work. . . . Courts should also consider the following factors in considering the question of whether a person is an agent or independent contractor: (1) the question of hiring; (2) the right to discharge; (3) the manner of direction of the servant; (4) the right to terminate the relationship; and (5) the character of the supervision of the work done. . . . The presence of one or more of the above facts and *indicia* are not necessarily conclusive of the issue.

Id. (internal quotations and citations omitted). TMC bears the burden of establishing an agency relationship. *Id*. It woefully failed to meet this burden.

In its brief, TMC states that "Mylan contracted with Biocon to do [its] manufacturing work," but gives no further explanation of why the Court should attribute Biocon's statements to Mylan. (TMC Resp. Br. at 5.) TMC does not even argue—let alone offer evidence—that any of the factors relevant to an agency determination under Illinois law exist. Thus, TMC provides no basis for the Court to admit Biocon's hearsay statements at trial or consider them on summary judgment. Furthermore, because TMC failed to submit evidence showing an agency relationship between Mylan and Biocon, even if the Court were to consider the Biocon documents at issue, the record is insufficient to allow a reasonable jury to attribute Biocon's statements to Mylan.

Second, even if the Court could attribute Biocon's statements to Mylan, TMC offers no evidence that the Biocon employee who authored the documents at issue intended the phrase "efficient stirring" to take on the specialized meaning in the patents-in-suit. TMC does not even offer evidence or argument to show that the Biocon employee knew the specialized meaning of "efficient mixing" contained in the patents-in-suit. Indeed, the Biocon employee's interchangeable use of synonymous phrases—"efficient stirring," "better stirring," and "adequate stirring"—suggest that she had used "efficient" in the ordinary sense of the word, not the technical sense espoused in the patents-in-suit.

The Federal Circuit considered a similar issue, albeit at a different stage in the proceeding, in *Rembrandt Vision Technologies, L.P. v. Johnson & Johnson Vision Care, Inc.*, 725 F.3d 1377 (Fed. Cir. 2013). In that case, Rembrandt Vision Technologies sued Johnson & Johnson Vision Care for infringement of its patent pertaining to a "soft gas permeable contact lens." *Id.* at 1379. During claim construction, the district court adopted that parties' agreed construction of "soft gas permeable contact lens" to mean "a contact lens having a Hardness (Shore D) less than five." *Id.* Shortly before trial, Rembrandt sought to admit Johnson & Johnson's "characterization of its lenses as 'soft'" as circumstantial evidence of infringement. *Id.* at 1382. The district court, however, excluded the evidence from trial because Johnson & Johnson's generic characterization of the accused lenses was not probative in light of the court's earlier construction of the term "soft." *Id.* at 1379. After striking the trial testimony of Rembrandt's expert witness under Federal Rule of Civil Procedure 37, the district court entered judgment as a matter of law for Johnson & Johnson, finding that Rembrandt failed to present evidence that the accused lenses were "soft." *Id.* at 1380. Rembrandt argued on appeal that the court erred in refusing to consider its circumstantial evidence of infringement. The Federal Circuit, however, affirmed the judgment of non-infringement, stating that "[g]eneric statements that the accused lenses are 'soft' had the potential to confuse the jury and did not bear on whether the accused lenses had a Shore D Hardness of less than five." *Id.* at 1383 (citing Fed. R. Evid. 403).

Likewise, Biocon's generic use of the term "efficient" to describe the stirring method used in Mylan's compounding process does not bear on whether Mylan used "efficient mixing,"

as defined in the patents-in-suit. Accordingly, TMC has failed to put forward sufficient evidence to allow a reasonable jury to treat Biocon's statements as admissions of infringement by Mylan.[8]

B. The '727 Patent Does Not Incorporate an "Efficient Mixing" Process Limitation

Mylan argues that TMC's inability to establish that Mylan uses "efficient mixing" also dooms TMC's infringement claim under the '727 patent. (Mylan Opening Br. at 15-18.) Unlike the '343 patent, the claims of the '727 patent do not expressly require the use of "efficient mixing." Mylan, however, contends that the Court's construction of the term "pharmaceutical batches" incorporates process elements into the asserted claims of the '727 patent that require the use of "efficient mixing." (*Id.* at 15-16.) Mylan further argues that because TMC disclaimed the use of "inefficient mixing" in the '727 patent specification and during patent prosecution, TMC cannot now argue that the '727 patent encompasses products generated through the use of "inefficient mixing." (*Id.* at 16-18.)

Claim interpretation is a matter of law for the Court to determine. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 391 (Fed. Cir. 1995) (*en banc*), *aff'd* 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996); *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1358 (Fed. Cir. 2012). The Court begins its claim construction analysis with the words of the claims themselves, giving those words their ordinary and customary meaning, *i.e.,* "the meaning

[8] On October 3, 2013, TMC filed a motion for leave to file a sur-reply, attaching its proposed sur-reply as an exhibit. (R. 303.) In TMC's proposed sur-reply, TMC cited to evidence purportedly showing that a principal-agent relationship existed between Mylan and Biocon. (*Id.* at Ex. 1, pp. 2-6.) The Court, however, denied TMC's motion for leave to file the proposed sur-reply on October 7, 2013. (R. 306.) The proposed sur-reply, even if the Court had allowed it, does not change the Court's opinion regarding whether the Court can attribute Biocon's hearsay statements to Mylan. Even if the sur-reply raised questions of fact regarding whether Biocon is an agent of Mylan, TMC's argument would still fail because of the lack of evidence indicating that Biocon used the term "efficient" as the Court construed it during claim construction. In fact, in her deposition, the Biocon employee who authored the documents at issue indicated that she had used the phrase "efficient stirring" generically to mean "better stirring," "proper stirring," or "adequate stirring." (R. 303, TMC Proposed Sur-Reply at 3.) TMC does not present any evidence contradicting this fact.

that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp*., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*); *see also InterDigital Comm'cns, LLC v. Int'l Trade Comm'n*, 690 F.3d 1318, 1333 (Fed. Cir. 2012). The Federal Circuit teaches that "[i]mportantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313; *see also HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1275 (Fed. Cir. 2012) (stating that the district court "should have referred to the specification to understand the claims" (citing *Phillips*, 415 F.3d at 1315)). Courts also look to the prosecution history of the patent-in-suit in interpreting disputed claims. *See HTC Corp.*, 667 F.3d at 1276 (citing *Phillips*, 415 F.3d at 1317). Additionally, if necessary, courts may consider "extrinsic evidence," which consists of "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises," to help "shed useful light on the relevant art." *See Phillips*, 415 F.3d at 1317 (citations omitted). Extrinsic evidence, however, is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* (internal quotations and citation omitted).

In its Claim Construction Order, the Court construed "pharmaceutical batches" as follows:

> "Pharmaceutical batches" may include a single batch, wherein the single batch is representative of all commercial batches (see generally, Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAPP 5225.1, Guidance on the Packaging of Test Batches at 1) made by a compounding process, and wherein the levels of, for example, Asp^9-bivalirudin, total impurities, and largest unknown impurity, and the reconstitution time represent levels for all potential batches made by said process. 'Batches' may also include all batches prepared by a same compounding process.

(Claim Construction Op. at 11, 30.) The parties disagree regarding whether the phrases "made by a compounding process," "made by said process," and "prepared by a same compounding process" necessarily incorporate an "efficient mixing" limitation into the asserted claims of the '727 patent.

1. Asserted Claims

None of the claims in the '727 patent expressly refers to an "efficient mixing" requirement or any other process requirement. While Claim 1 of the '343 patent expressly includes certain process limitations, including an "efficient mixing" limitation, those process limitations are noticeably absent from Claim 1 of the '727 patent. (*Compare* '343 patent at col. 27, ll. 13-31 *with* '727 patent at col. 25, ll. 57-64.) Indeed, the lack of process limitations in the '727 patent is the only difference between the claims in the '727 patent and those in the '343 patent. (*Compare* '343 patent at col. 27 l. 12 – col. 28 l. 63 *with* '727 patent at col. 25 l. 55 – col. 28 l. 24.) TMC argues that incorporating the absent process elements into the '727 patent's claims would "vitiate the distinctions between the '727 patent's product claims and the '343 patent's product-by-process claims." (TMC Resp. Br. at 22.)

On the other hand, although the claims in the '727 patent do not contain any express process limitations, the definition of "pharmaceutical batches" contained in the specification repeatedly refers to the use of a compounding process. (*See* '727 patent at col. 5, ll. 24-36.) Specifically, the specification defines a "batch" or "pharmaceutical batch" as follows:

> As used here, "batch" or "pharmaceutical batch" refers to material *produced by a single execution of a compounding process of various embodiments of the present invention*. "Batches" or "pharmaceutical batches" as defined herein may include a single batch, wherein the single batch is representative of all commercial batches (see generally, Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAPP 5225.1, Guidance on the Packaging of Test Batches at 1), and wherein the levels of, for example, Asp^{9}-bivalirudin, total impurities, and largest unknown impurity, and the reconstitution time represent

> levels for all potential batches *made by said process*. "Batches" may also include all batches *prepared by a same compounding process*.

(*Id.* (emphasis added).) During claim construction briefing, TMC even admitted during claim construction briefing that "[w]hen viewed in the context of the specification, it is readily apparent that the [definition of 'pharmaceutical batches'] refers to the compounding processes described in the patents-in-suit." (TMC Claim Construction Sur-Reply at 2.)

"Pharmaceutical batch" appears either expressly or by incorporation in every claim of the '727 patent. (*See* '727 patent at col. 25 l. 54 – col. 28 l. 23.) Mylan argues that, as a result, the asserted claims, when viewed in light of the definition of "pharmaceutical batches," incorporate various process limitations, including an "efficient mixing" limitation. (Mylan Reply Br. at 9-10.)

2. Patent Specification and Prosecution History

Both parties contend that the '727 patent specification and its prosecution history lend support to their respective positions. Mylan argues that the specification and prosecution history show that "the applicants repeatedly disavowed any compounding process that does not 'efficiently mix' the pH-adjusting solution and the bivalirudin solution." (Mylan Opening Br. at 16-18.) TMC, on the other hand, argues against disavowal, asserting that although the specification and prosecution history describe preferred embodiments that include "efficient mixing," they notably do not mandate the use of "efficient mixing." (TMC Resp. Br. at 22-25.) Statements made in the prosecution history of a patent can only amount to a disclaimer if the applicants "'clearly and unambiguously' disavowed claim scope." *See, e.g., Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1370 (Fed. Cir. 2012) (citing *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1370-71 (Fed. Cir. 2003)); *Computer Docking Station Corp. v.*

Dell, Inc., 519 F.3d 1366, 1375 (Fed. Cir. 2008) ("Prosecution disclaimer does not apply to an ambiguous disavowal.").

In support of its argument, Mylan points to several purported disclaimers of "inefficient mixing" conditions in the '727 patent specification. First, Mylan argues that the contrast between the "inefficient mixing" conditions used in Example 4 and the "efficient mixing" conditions used in Example 5 serves as the "focal point" of the '727 specification. (Mylan Opening Br. at 16-17.) Second, Mylan points out that no claim in the '727 patent permits a maximum Asp^9-bivalirudin impurity level above the maximum level of Asp^9-bivalirudin impurities produced using the "efficient mixing" conditions in Example 5. (Mylan Opening Br. at 16-17.) Third, Mylan notes that the '727 patent specification attributed the consistently reduced levels of Asp^9-bivalirudin impurities in invention at issue to the use of "efficient mixing," and identified "inefficient mixing" conditions as the source of greater levels of Asp^9-bivalirudin impurities in prior art. (*See id.* at 17; *see also, e.g.,* '727 patent at col. 9 ll. 34-35 ("Efficient mixing is characterized by minimizing levels of Asp^9-bivalirudin in the compounding solution.").) "From this," Mylan argues, "it is clear that the 'inefficient mixing' process of Example 4 is disclosed as a prior art process that falls *outside* the scope of the patent claims." (Mylan Opening Br. at 17.)

Mylan also cites to purported examples of disclaimer in the prosecution history of the '727 patent. In the Petition to Make Special for the '727 patent, the applicants differentiated between the claimed invention, which the applicants generated using this new "efficient" compounding process, from original Angiomax® formed using the old "inefficient" compounding process:

> In the present invention, various embodiments relate to a less subjective and more consistent process for the mixing of the pH-adjusting solution with the

> bivalirudin solution. This process involves efficiently mixing the pH-adjusting solution and the dissolved bivalirudin solution, which is not performed in the Applicants' prior compounding process.
>
> In addition, pharmaceutical batch(es) and pharmaceutical formulation(s) of bivalirudin formed by the new compounding process are distinguished from the batches and formulations of bivalirudin formed by the prior compounding process. The pharmaceutical batch(es) and pharmaceutical formulation(s) associated with the present compounding process are more consistent and have a maximum level of Asp^9-bivalirudin of about 0.6% w/w (a decrease of about 83% compared to the batches or formulations made by the prior process), a maximum reconstitution time of about 42 seconds (a decrease of about 42% compared to the batches or formulations made from the prior process), and a maximum amount of total impurities of about 2.0% (a decrease of about 33% compared to the batches or formulations made by the prior process), for all batches or formulations made by the new process.

(Greb Decl. Ex. 19 at 3.)

The applicants expressly noted the absence of "efficient mixing" conditions in distinguishing the "Tovi" (U.S. Publication No. 20070093423) and "EMEA" (Angiox®) prior art as well. To distinguish the "Tovi" reference, the applicants stated:

> The [Tovi] application is silent regarding a compounding process via the addition of a pH-adjusting solution to the bivalirudin solution in a controlled manner with efficient mixing as to avoid the formulation of Asp^9-bivalirudin during the compounding stage. The [Tovi] specification does not state how much Asp^9-bivalirudin is present in the final formulated unit dosage forms or generated during the compounding process. Further, the [Tovi] application is silent regarding the maximum amount of unknown impurity levels and reconstitution time for the bivalirudin drug product.

(*Id.* at 6 (emphasis added).) The applicants distinguished the "EMEA" reference on similar grounds:

> [T]he EMEA publication discloses that the bivalirudin drug substance is compounded, but does not provide a disclosure of how the drug substance was compounded. The EMEA publication also discloses that over thirty batches have been prepared. . . . It is important to note that the manufacture of these bivalirudin batches were [sic] <u>not</u> performed using the inventive process of the present invention.

(*Id.* at 9 (emphasis in original).) Mylan argues that "[t]hese statements in the '727 patent specification and its prosecution history operate as a clear and undeniable waiver of claim scope[,] [and] TMC cannot now contend that the claims of the '727 patent encompass the 'inefficient mixing' that it expressly disclaimed." (Mylan Opening Br. at 17-18.)

In opposition, TMC cites various instances in the specification and the prosecution history where the applicants referred to embodiments of the claimed bivalirudin drug product without discussing the process used to develop the drug. (TMC Resp. Br. at 22-25.) TMC points out that although the '727 specification refers to some embodiments of the claimed invention as pertaining to a method for preparing pharmaceutical batch(es) or pharmaceutical formulation(s) of the bivalirudin drug product, it describes other embodiments without reference to the method of production. (*See, e.g.,* the '727 patent at col. 1, ll. 24-27 ("Some embodiments of the present invention are also directed towards a pharmaceutical batch(es) or pharmaceutical formulation(s) comprising bivalirudin as the active ingredient."); *id.* at col. 3 ll. 21-24 ("In certain embodiments, the pharmaceutical batch(es) or pharmaceutical formulation(s) is characterized by a maximum impurity level of Asp^9-bivalirudin that does not exceed about 0.6%").) Similarly, in the Petition to Make Special, although the applicants differentiated the claimed invention from prior art based on the absence of efficient mixing, they also stated that their new bivalirudin final drug product had lower and more consistent impurity levels and reconstitution times than prior art. (*See, e.g.,* Greb Decl. Ex. 19 at 6 ("[T]he [Tovi] application is silent regarding the maximum amount of unknown impurity levels and reconstitution time for the bivalirudin drug product.").) Specifically, the applicants distinguished each prior art reference on the grounds that the prior art did not describe:

> (1) pharmaceutical batches of a drug product comprising bivalirudin characterized by a maximum impurity level of Asp^9-bivalirudin not exceeding about 0.6% w/w

> for all batches; or (2) pharmaceutical batches of a drug product comprising bivalirudin, characterized by a maximum reconstitution time not exceeding about 42 seconds for all batches.

(*Id.* at 5-10.)

TMC argues that these repeated references to the physical properties of the new bivalirudin drug product without respect to the process used to generate it affirm that the '727 patent is a pure product patent, not a product-by-process patent like the '343 patent. (TMC Resp. Br. at 22-25.) TMC contends that the '727 patent describes *preferred* embodiments of the invention that involve "efficient mixing," but does not require the use of "efficient mixing" conditions in manufacturing the claimed drug product, like the '343 patent does. (*Id.* at 24.) Thus—TMC argues—the Court should not convert the product claims in the '727 patent into process claims. (*Id.* at 23 (citing *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000)).)

3. The Court's Construction

As an initial matter, the Court notes that much of the difficulty inherent in delineating the scope of the '727 patent stems from the near identical patent specifications and prosecution histories for the '727 and '343 patents. The patents' specifications and Petitions to Make Special give short shrift to the differences between the two patents-in-suit. Instead, the applicants appear to have copied and pasted full sections from one patent's specification and Petition into the other patent's documents, and then simply changed a few concluding sentences. Based on the totality of the evidence in the record, however, the Court finds that the '727 patent does not include an "efficient mixing" limitation.

The Federal Circuit has repeatedly warned that "[c]ourts must generally take care to avoid reading process limitations into [a product] claim . . . because the process by which a product is made is irrelevant to the question of whether that product infringes a pure [product]

claim[.]" *See AstraZeneca LP v. Breath Ltd.*, --- Fed. App'x ----, 2013 WL 5813759, at *5 (Fed. Cir. Oct. 30, 2013) (unpublished opinion) (quoting *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1344 (Fed. Cir. 2008)); *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 873 (Fed. Cir. 2010) (same). Generally, "[t]he method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process . . . . A novel product that meets the criteria of patentability is not limited to the process by which it is made." *AstraZeneca*, 2013 WL 5813759, at *5 (ellipsis in original) (quoting *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000)).

An applicant, however, may disclaim products created using certain processes if the applicant "overcomes a rejection against [both] product and process claims by indicating that the process is necessary to produce the claimed product" and, in doing so, fails to "limit the disclaimers to [only] the process claims." *Id.* (citing *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384-85 (Fed. Cir. 2005)). Prosecution disclaimer requires "clear and unambiguous disavowal of claim scope." *Saffran v. Johnson & Johnson*, 712 F.3d 549, 559 (Fed. Cir. 2013) (quoting *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 833 (Fed. Cir. 2003)); *Toshiba Corp.*, 681 F.3d at 1370 ("A statement in the prosecution history can only amount to disclaimer if the applicant 'clearly and unambiguously' disavowed claim scope."). Accordingly, prosecution disclaimer does not apply "if the applicant simply describes features of the prior art [but] does not distinguish the claimed invention based on those features." *Computer Docking Station Corp.*, 519 F.3d at 1375 (citing *Eolas Techs., Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1337 (Fed. Cir. 2005)).

The question for the Court is whether TMC's purported disavowal of bivalirudin final drug products manufactured using "inefficient mixing" was sufficiently "clear and

unambiguous" to justify reading in an "efficient mixing" limitation into the asserted claims in the '727 patent. The Court concludes that it was not.

To begin with, the claims of the '727 patent do not expressly include process limitations, which weighs against reading process limitations into them. *See, e.g., Combined Sys., Inc. v. Defense Tech. Corp. of Am.,* 350 F.3d 1207, 1210 (Fed. Cir. 2003) ("[T]he claim construction inquiry . . . begins and ends in all cases with the actual words of the claim."). Despite the similarities between the '727 and the '343 patents, the claims of the '727 patent notably exclude the process limitations that are present in the claims of the '343 patent. Furthermore, even though the applicants submitted nearly identical Petitions to Make Special for the two patents, they made an effort to differentiate between the product claims in the '727 patent and the product-by-process claims in the '343 patent in the concluding sentence of each section distinguishing prior art. (*Compare* Greb. Decl. Ex. 19 at 5-10 *with* Greb Decl. Ex. 20 at 4-13.) In the '727 petition, the applicants concluded each section by stating that the prior art reference did not describe the improved impurity levels and reconstitution times that characterized the claimed invention—*i.e.,*the physical characteristics the invented product at issue—whereas in the '343 petition, the applicants concluded each section by stating that the new "efficient mixing" process used to generate the invention at issue distinguished it from prior art. (*Compare* Greb. Decl. Ex. 19 at 5-10 *with* Greb Decl. Ex. 20 at 4-13.) These distinctions between the '727 and '343 patents and in their prosecution histories indicate that the '727 patent is a pure product patent, *cf. Baldwin Graphic Sys.,* 512 F.3d 1338 ("Claim 1 and its dependent claims . . . are pure apparatus claims. They have no process limitations[,] [and] . . . are therefore not limited to any particular process or method of making the claimed [invention.]"), whereas the '343 patent is a product-by-process patent. Accordingly, because the applicants' purported disavowal of

bivalirudin final drug products in the prosecution of the '727 patent is ambiguous, the doctrine of prosecution disclaimer does not apply. *See, e.g., 3M Innovative Props. Co. v. Avery Dennison Corp.,* 350 F.3d 1365, 1373 (Fed. Cir. 2003) (finding that remarks made in the prosecution history did not constitute "the clear and unambiguous disavowal of claim scope that is required to read a limitation into an expressly defined term"); *see also Toshiba Corp.,* 681 F.3d at 1370; *AstraZeneca LP*, 2013 WL 5813759, at *5.

Furthermore, while on first read the definition of "pharmaceutical batches" appears to incorporate the process elements of "efficient mixing" described in the patent specification into the '727 patent's claims, the definition likely refers to "a compounding process" to distinguish it from prior art. Asp^9-bivalirudin impurities in a bivalirudin final drug product can form at two steps in the manufacturing process: (1) during the synthesis of the bivalirudin API and (2) during the compounding process that adjusts the pH level of the bivalirudin API to make it suitable for injection into patients. (*See* '727 patent at col. 2 ll. 8-23.) Prior art, including the "Tovi" reference, encompassed methods for minimizing the generation of Asp^9-bivalirudin impurities during the synthesis of the bivalirudin API. (*See id.; see also* Greb Decl. Ex. 19 at 6-7.) By specifying that a "pharmaceutical batch" consisted of material "produced by . . . a compounding process of various embodiments of the present invention," the patent distinguished the properties of the claimed invention from the properties of bivalirudin APIs generated in prior art. The "Tovi" prior art, for example, disclosed "the synthetic preparation of bivalirudin"—*i.e.,* the bivalirudin API—"having not more than 0.5% Asp^9-bivalirudin." (*See* Greb Decl. Ex. 19 at 6.) In the Petition to Make Special, the applicants distinguished the "Tovi" prior art on the grounds that the "Tovi" reference did not state the amount of Asp^9-bivalirudin impurities that existed in the *final* drug product after it underwent the necessary compounding process. (*See id.* ("The

[Tovi] application does not state how much Asp^{9}-bivalirudin is present in the final formulated unit dosage forms or generated during the compounding process.").)

For these reasons, the Court is unpersuaded that the inclusion of the phrase "made by a compounding process" or similar in the definition of "pharmaceutical batches" incorporates process elements into the asserted claims of the '727 patent. The Court, therefore, holds that the '727 patent does not contain an "efficient mixing" limitation.

C. Factual Disputes Regarding the Maximum Level of Asp^{9}-Bivalirudin in Mylan's Proposed Final Drug Product Preclude Summary Judgment

To prevail on its claim of infringement of the '727 patent, TMC must prove, among other things, that the batches made using Mylan's compounding process will have a maximum impurity level of Asp^{9}-bivalirudin that does not exceed about 0.6% as measured by HPLC. ('727 patent at Claim 1); *see Riles,* 298 F.3d at 1308 ("To prove literal infringement, the patentee must show that the accused device contains every limitation in the asserted claims." (quoting *Mas-Hamilton Grp.,* 156 F.3d at 1211)). TMC bases its infringement contentions with respect to this element on the Asp^{9}-bivalirudin impurity level of 0.2% in the exhibit batch Mylan submitted to the FDA in conjunction with its ANDA. (TMC Resp. Br. at 11-13.) Mylan argues that the impurity levels in its exhibit batch fail to create a genuine issue of material fact because "a single batch is insufficient to predict the results of future batches." (Mylan Opening Br. at 20.)

In an action, like this one, brought under § 271(e)(2)(A) of the Hatch-Waxman Act, the focus of the infringement inquiry is on "what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." *Bayer AG v. Elan Pharm. Res. Corp.,* 212 F.3d 1241, 1248 (Fed. Cir. 2000). Thus, the infringement analysis under § 271(e)(2)(A) is necessarily a "hypothetical inquiry . . . properly grounded in the ANDA application and the extensive materials typically submitted in its support." *Id.* (quoting *Glaxo, Inc. v. Novopharm,*

Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997)). "Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a way that directly addresses the issue of infringement will control the infringement inquiry." *Abbott Labs. v. TorPharm, Inc.,* 300 F.3d 1367, 1373 (Fed. Cir. 2002); *see also Bayer,* 212 F.3d at 1249. If, on the other hand, the ANDA specification does not define the drug in a manner that directly addresses the issue of infringement, the court may look to evidence outside the ANDA, including sample products submitted to the FDA, to decide the issue of infringement. *Bayer,* 212 F.3d at 1250 (citing *Glaxo,* 110 F.3d at 1569-70).

Here, Mylan's ANDA specification, which sets a maximum Asp^9-bivalirudin impurity level of 2.0%, does not "directly address the issue of infringement" because a product with an Asp^9-bivalirudin level of 0.3%, for example, may comply with the ANDA specification and, at the same time, infringe the claims of the '727 patent. *See Ortho-McNeil Pharm., Inc. v. Kali Labs., Inc.,* 482 F. Supp. 2d 478, 501 (D.N.J. 2007) (explaining that a court need not examine evidence outside the ANDA specification if the scope of the compound described in the ANDA falls either entirely inside the scope of the patent or entirely outside the scope of the patent), *aff'd in part and vacated in part on other grounds in* 344 Fed. App'x 595 (Fed. Cir. 2009). TMC, therefore, may rely on the exhibit batch Mylan submitted to the FDA to prove infringement. *See Bayer,* 212 F.3d at 1250; *Glaxo,* 110 F.3d at 1569-70.

Even so, Mylan argues that TMC fails to establish a genuine issue of material fact regarding whether future batches made using Mylan's ANDA process will infringe the '727 patent because "[a] single batch result cannot reliably predict the results of future batches." (Mylan Opening Br. at 20-22.) Mylan's argument, however, fails to account for the special

nature of the "single batch" at issue here. Because "ANDAs . . . are usually approved based on data from a single test batch," the FDA Manual of Policies and Procedures stresses that "[i]t is critical that all testing be conducted on samples that represent the entire batch and mimic the product which will be marketed post-approval." *See* Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAP 5225.1, Guidance on the Packaging of Test Batches at 1. Here, Mylan submitted an exhibit batch in conjunction with its ANDA that had an Asp^9-bivalirudin impurity level of 0.2%, which falls below the maximum level of Asp^9-bivalirudin impurities in the asserted claims. Mylan admits that it will manufacture its proposed commercial product in the same manner as Biocon manufactured the exhibit batch, except on a larger scale. (Mylan L.R. 56.1 Stmt. ¶ 71; *see also* Fleming Decl. Ex. 16 at MYL0000212.) Viewing this evidence in the light most favorable to TMC and drawing all reasonable inferences in its favor, the Court finds that TMC has offered sufficient evidence to establish a genuine issue of material fact, especially in light of the inherently "hypothetical inquiry" involved in an infringement determination under § 271(e)(2)(A). *See Connetics Corp. v. Agis Indus. (1983) Ltd.*, Civ. No. 05-5038, 2008 U.S. Dist. LEXIS 31646, at *7 (D.N.J. Apr. 14, 2008) (denying summary judgment of non-infringement where the pH level of one of the several "development batches" the defendant submitted with its ANDA fell within the claims of the patent-in-suit).

Mylan offers a plethora of evidence in support of its argument that a single exhibit batch cannot reliably predict the results of future batches, including expert opinions, testimony from one of the inventors, and data from TMC's own prior art. (*See* Mylan Opening Br. at 20-22.) The Court's role on summary judgment, however, is not to "weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson,* 477 U.S. at 249; *see also United States v. Funds in Amount of One Hundred Thousand One Hundred*

& Twenty Dollars ($100,120.00), 730 F.3d 711, 717 (7th Cir. 2013) ("At summary judgment, whether the movant's evidence is more persuasive than the evidence of the non-movant is irrelevant."). The Court, therefore, denies Mylan's motion for summary judgment of non-infringement with respect to the '727 patent.

II. Invalidity of the '727 Patent

Mylan moves, in the alternative, for summary judgment of invalidity with respect to the '727 patent. Mylan argues that if the Court determines that the '727 patent does not require the use of "efficient mixing"—which it has—the patent is invalid under 35 U.S.C. § 112, paragraph 1 for lack of enablement and written description.[9] Because patents are presumed valid, *see* 35 U.S.C. § 282, Mylan must prove invalidity by clear and convincing evidence. *Microsoft Corp v. i4i Ltd. P'ship,* --- U.S. ----, 131 S. Ct. 2238, 2245, 180 L. Ed. 2d 131 (2011).

The enablement requirement in 35 U.S.C. § 112 mandates that a patent specification describe "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention]." *Liebel-Flarsheim Co. v. Medrad, Inc.,* 481 F.3d 1371, 1378 (Fed. Cir. 2007) (internal quotations and citation omitted; alterations in original). To satisfy the enablement requirement, "the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Teva Pharms. USA v. Sandoz, Inc.,* 723 F.3d 1363, 1370 (Fed. Cir. 2013); *see also AK Steel Corp. v. Sollac & Ugine,* 344 F.3d 1234, 1241 (Fed. Cir. 2003)

[9] Mylan also argues that if the Court interprets the '727 patent to encompass batches that "consistently," but not always, have maximum Asp[9]-bivalirudin impurity levels of 0.6%, the '727 patent is invalid due to anticipation by TMC's original Angiomax® product. (Mylan Opening Br. at 22-24.) Neither party has advanced this interpretation of the '727 patent. In fact, both have argued against reading "consistently" into the asserted claims. (*See id.* at 22; TMC Resp. Br. at 28, 31.) The Court, therefore, does not need to address this argument.

("[A] patent specification must enable the full scope of a claimed invention."). "Whether a claim satisfies the enablement requirement of 35 U.S.C. § 112 is a question of law." *Liebel-Flarsheim,* 481 F.3d at 1377.

The closely-related written description requirement of 35 U.S.C. § 112, paragraph 1 "requires a patentee to provide a written description that allows a person of skill in the art to recognize that the patentee invented what is claimed." *Synthes USA, LLC v. Spinal Kinetics, Inc.,* 734 F.3d 1332, 1341 (Fed. Cir. 2013). "[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor ha[d] possession of the claimed subject matter as of the filing date." *Id.* (alteration in original). "The level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Id.* "Compliance with the written description requirement is a question of fact but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *Trading Techs. Int'l, Inc. v. Open E Cry, LLC,* 728 F.3d 1309, 1318 (Fed. Cir. 2013) (internal quotations and citation omitted).

According to Mylan, if the '727 patent encompasses pharmaceutical batches generated using "inefficient mixing" in addition to batches generated using "efficient mixing," the patent is invalid because it fails to enable the full scope of the claimed invention—specifically, batches generated through "inefficient mixing." (Mylan Opening Br. at 26.) Mylan further claims that the '727 patent fails to satisfy the written description requirement because it does not convey that the inventors had possession of any embodiment of the invention that used "inefficient" mixing to achieve the claimed Asp^9-bivalirudin levels. (*Id.*) Mylan's arguments rest on the faulty premise that the claims in the '727 patent speak to process limitations at all.

The ’727 patent is a product patent. The invention in the ’727 patent is a bivalirudin drug product having the characteristics described in the patent, not a bivalirudin drug product made using a specific process (efficient or otherwise). *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.,* 314 F.3d 1313, 1329 (Fed. Cir. 2003) (“[P]roduct claims . . . are directed to a structural entity that is not defined or limited by how it is made.”). As a result, the process used to generate the claimed drug “is immaterial and ‘legally irrelevant’ . . . and cannot be relied on as a basis to render the[] . . . claims invalid for lack of enablement.” *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.,* 648 F. Supp. 2d 1294, 1342-43 (M.D. Fla. 2009); *see also Johns Hopkins Univ. v. CellPro, Inc.,* 153 F.3d 1342, 1361 (Fed. Cir. 1998) (“[T]he enablement requirement is met if the description enables any mode of making and using the invention.” (citation omitted)); *Invitrogen Corp. v. Clontech Labs., Inc.,* 429 F.3d 1052, 1071 (Fed. Cir. 2005) (“Although Clontech’s validity argument might have force had Invitrogen limited its claims to modified RT by reference to point mutation, Clontech overlooks the fact that the claims are not limited by the method of achieving the mutation.” *Durel Corp. v. Osram Sylvania Inc.,* 256 F.3d 1298, 1307 (Fed. Cir. 2001) (“[I]f the patent specification enabled a person of ordinary skill in the art to make the claimed titanium dioxide coating from a titanium tetrachloride precursor, it would be irrelevant for purposes of validity if the patent specification did not enable its preparation from a titanium isopropoxide precursor.”). The Court therefore rejects Mylan’s argument that the ’727 patent’s failure to describe how to generate the claimed bivalirudin drug product using “inefficient mixing” renders it invalid.

The Court rejects Mylan’s argument for invalidity due to an inadequate written description for the same reason. *Cf. LizardTech, Inc. v. Earth Resource Mapping, Inc.,* 424 F.3d 1336, 1345 (Fed. Cir. 2005) (noting that the enablement and written description requirements

"usually rise and fall together"). The patent need only show that the inventors had possession of the claimed invention—a bivalirudin drug product having the characteristics described in the patent—not a bivalirudin drug product generated by "inefficient mixing." Mylan does not argue that the patent failed to convey to those skilled in the art that the inventors had possession of a bivalirudin drug product having, for example, a maximum Asp^9-bivalirudin impurity level of 0.6%. Accordingly, the Court rejects Mylan's argument for invalidity on the grounds of inadequate written description, and denies Mylan's motion for summary judgment of invalidity with respect to the '727 patent.

III. TMC's Claim of Willful Infringement

Finally, Mylan moves for summary judgment with respect to TMC's willful infringement claim. (Mylan Opening Br. at 26-28.) In its opening brief, Mylan argued that TMC cannot prove willful infringement because (1) "the filing of an ANDA alone does not support a finding of willful infringement" and (2) "TMC cannot show that Mylan's actions were objectively unreasonable." (Mylan Opening Br. at 27.) TMC maintains that Mylan misunderstands its claim for willful infringement, which TMC bases "on acts that may occur in the future," not on actions that Mylan has taken to date. (TMC Resp. Br. at 34.) In other words, TMC claims that Mylan will willfully infringe the patents-in-suit "***if*** Mylan commercially manufactures, uses, sells, offers to sell, or imports its generic bivalirudin product in the future." (*Id.* (emphasis in original).)

TMC, however, does not cite any authority suggesting that this type of declaratory relief is appropriate. Nor does TMC cite any facts to warrant this type of declaratory relief. "Perfunctory and undeveloped arguments, and arguments that are unsupported by pertinent authority, are waived." *United States v. Hook*, 471 F.3d 766, 775 (7th Cir. 2006). The Court, therefore, grants Mylan's motion for summary judgment with respect to TMC's willful

infringement claim. *See Giffney Perret, Inc. v. Matthews*, No. 07 C 0869, 2009 WL 792484, at *16 (N.D. Ill. Mar. 24, 2009) (granting partial summary judgment to the defendant because the plaintiff's "undeveloped arguments amount[ed] to a waiver of Plaintiff's opposition to Defendants' motion for summary judgment").

CONCLUSION

For the reasons explained above, the Court grants Mylan's motion for summary judgment of non-infringement with respect to the '343 patent but denies it with respect to the '727 patent. The Court also denies Mylan's alternative motion for summary judgment as to invalidity of the '727 patent. Finally, the Court grants Mylan's motion for summary judgment regarding TMC's claim for willful infringement.

Dated: December 16, 2013

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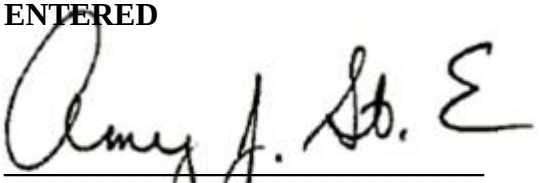

AMY J. ST. EVE
U.S. District Court Judge